Transparency through the lens of data protection and privacy: A clinical research organisation medical writing perspective

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doi: 10.56012/vmom7031

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Abstract

Medical writers maintain a fine balance between data transparency obligations and personal data protection in clinical reports. Hence, we must stay informed of data protection requirements outlined in the EU General Data Protection Regulation (GDPR) 2016/679 and their interaction with data transparency requirements of the EU Clinical Trials Regulation (EU-CTR) 536/2014 and EMA Policy 0070. Medical writers need to understand the core concept of personal data versus anonymised data and the differences between working for a data controller versus working for a data processor.

This article explores how a clinical research organisation, as the data processor, assists client companies, as the data controller, fulfil transparency obligations, illustrated by a successful collaboration model. We examine how medical writers contribute to an organisation's disclosure-readiness as well as promote the value of a disclosure-informed medical writer's upstream impact as clinical reports anonymisation specialists throughout the clinical trial lifecycle.

In the clinical research context, protecting the confidentiality of research subjects' identity has always been a fundamental ethical consideration, increasingly challenged by complexities in electronic data collection, storage, and the re-use of data from various sources, including the data transparency requirements of the EMA Policy on the publication of clinical data for medicinal products for human use (hereafter referred to as "EMA Policy 0070") and the EU Clinical Trials Regulation 536/2014 (EU-CTR). In this article, we explore the interplay between the EU GDPR 2016/679, Phase 1 of EMA Policy 0070, and the EU-CTR and how these now impact clinical research organisation (CRO) medical writers (MWs).

Basic GDPR terms

The EU GDPR applies to the processing of personal data[1] by data controllers and data processors:[2]

- Personal data means any information relating to an identified or identifiable natural person...
- The GDPR does not apply to the processing of fully anonymised data. According to GDPR Recital 26 "The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes".
- The GDPR mainly assigns the GDPR compliance accountability to the data controller – the natural or legal person, who, alone or jointly with others, determines the purposes and means of the processing of personal data.
- A data controller may employ the services of a data processor – a natural or legal person who processes personal data on behalf of the data controller and based on the data controller´s documented instructions.

> As data processors, medical writers play a key role in protecting data.

Interplay between EU-CTR and the GDPR on transparency

The EU-CTR requires information stored in the Clinical Trials Information System (CTIS) database to be publicly available but provides exceptions for such matters as the protection of personal data. To comply with EU-CTR transparency obligations, the reported and published data should be fully anonymised. The GDPR provides only a conceptual definition of anonymisation, necessitating the need for further guidance. As stated by the EMA's external guidance on the implementation of the EMA Policy 0070:

> *... there is a need for further guidance in order to ensure that Policy 0070 meets its objectives. For this purpose, EMA has prepared the following documents... External guidance on the anonymisation of clinical reports for the purpose of publication in accordance with EMA Policy 0070 (see Chapter 3).*[3]

So where do medical writers fit in?

Medical writers prepare most of the clinical reports that are required to be published under transparency regulations like EMA Policy 0070 and EU-CTR.

Some of the core attributes of MWs include data-centricity, time-bound efficiency, flexibility, and commitment to quality, all while striving for organisational simplicity. Therefore, it is not surprising that writers have evolved into the role of performing clinical reports anonymisation tasks as agreed between clients/sponsors as data controllers and CROs as data processors. Data privacy goes beyond Good Clinical Practice and ethical considerations in clinical research, and a MW's role in preserving it needs to be explored further. MWs have implemented some technical, organisational, and information technology

measures. As data processors, MWs play a key role in protecting data. Their expertise in anonymisation techniques and understanding of regulatory requirements make them essential contributors to maintaining privacy standards in clinical reports.[4]

The role of a data processing agreement between a CRO and sponsor

To understand how CROs may best collaborate with clients or sponsors while performing EMA Policy 0070/EU-CTR tasks, we need to first characterise a CRO's responsibilities regarding the anonymisation of clinical reports on behalf of the data controller:

- Only a data controller (the sponsor) decides how that anonymisation and data utility will play together.
- CROs act as data processor for the processing of study data but also for the anonymisation of clinical reports because the function of "anonymisation" of personal data in clinical reports is essentially the processing of personal data for the purpose of anonymising such data.
- Data processors do not make decisions on behalf of data controllers and are bound to follow the data controller's instructions. The CRO may make suggestions as to how the anonymisation of personal data could be made technically possible, but the decision for how personal data will be anonymised for protection must come from the sponsor as data controller.
- The GDPR requires that a data controller execute a data processing agreement with a data processor to govern the processing of personal data by the data processor on behalf of the data controller.[5]
- So how does this collaboration between data controller and data processor work? This article explores this from the medical writing perspective.

Box 1. Success factors in anonymisation projects

Medical Writer Expertise

- Familiarity with report structure and content
- Keen eye for analytical detail
- Technological agility, including familiarity with AI tools
- Extensive experience in anonymisation techniques and data protection requirements
- Established working relationship with long term clients

Clear Communication

- Set clear expectations: Clear scope, timelines, deliverables, and specific considerations
- Facilitate end-to-end collaboration
- Reduce risk of redaction proposal rejection
- Minimise delays and rework

Use of AI Tools

- Enable processing of large number of documents
- Streamline data handling
- Shorten timelines
- Improve accuracy

Lessons from CRO medical writers as anonymisation specialists

Even though a multifunctional team is likely to be involved in an EMA Policy 0070/EU-CTR task, MWs in their role as anonymisation specialists can add significant value. Success factors in anonymisation projects are presented in Box 1.

Project kick-off: Anonymisation projects may be initiated with a kick-off meeting to ensure a comprehensive understanding of client requirements thereby fostering trust with a well-trained and skilled team. Clear communication of expectations between the MWs (as anonymisation specialist) and clients is crucial, positioning the project for success before initiating the actual task. The key goals of the kick-off process are stakeholder orientation, and

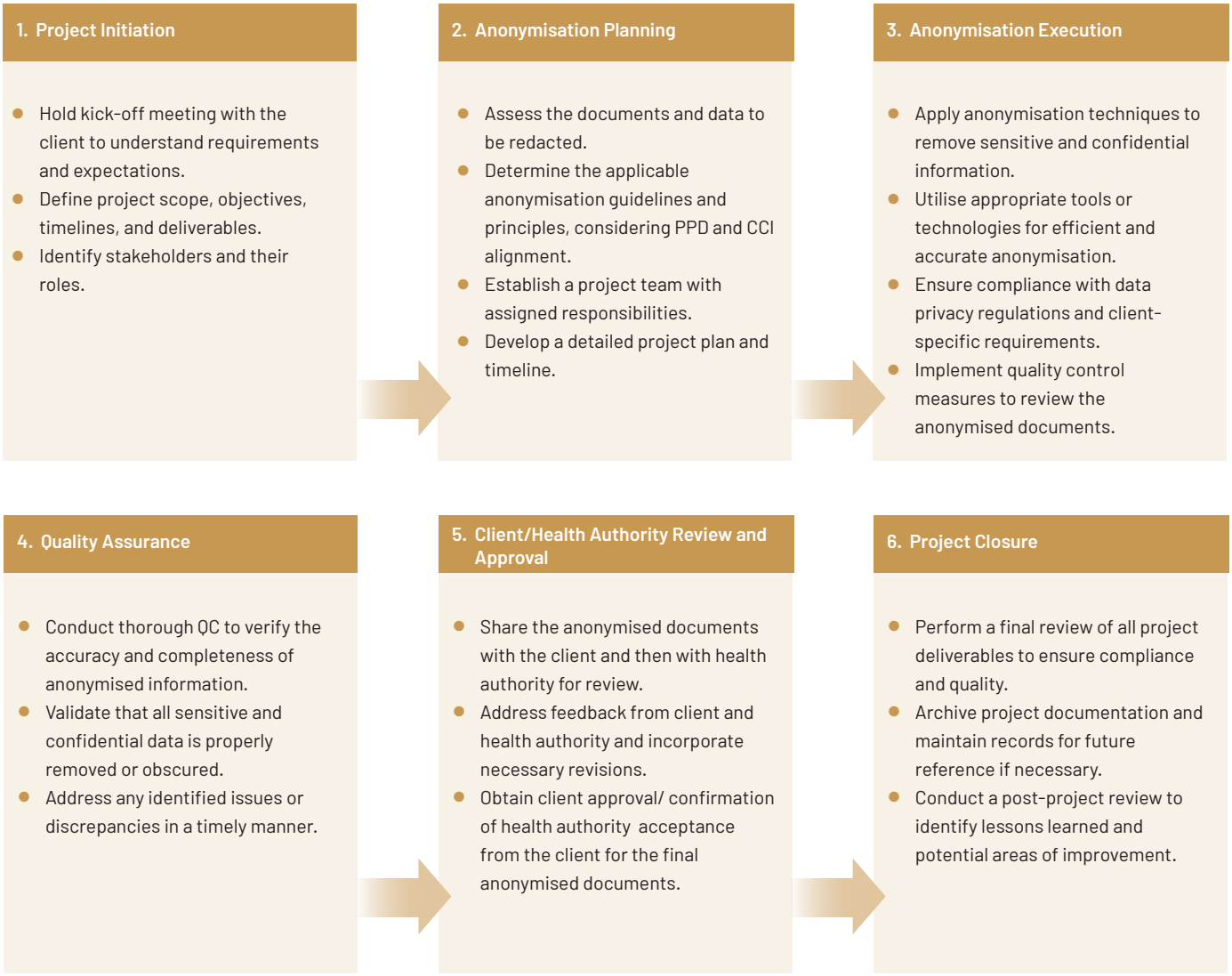

Figure 1. Schematic of the anonymisation process

Abbreviations: CCI, commercially confidential information; PPD, protected personal data; QC, quality control

project standardisation, and quality management.

Before commencing the anonymisation task, project-level guidelines to ascertain protected personal data (PPD) and commercially confidential information (CCI) in the clinical reports package should be agreed upon in writing. A schematic of the anonymisation process is shown in Figure 1.

Communication: Queries raised by a MW during the anonymisation process should be carefully handled by leveraging anonymisation-specific internal and external expertise, best practices, and lessons learned before generating queries to the client, and ensuring a thorough internal review. Clear and prompt communication is crucial, highlighting the importance of soft skills.

Document sharing: The clinical reports should be shared for client review via secure communication channels as agreed with the client.

Consultancy: MWs play a vital role in providing consultancy on the anonymisation process by leveraging their expertise in medical writing, regulatory guidelines, and clinical reports anonymisation.

Quality control: The QC process for anonymisation entails meticulously verifying the consistency and accuracy of anonymised information, ensuring that the final clinical reports' anonymised text is neither searchable nor editable, and conducting comprehensive checks on metadata, file properties, and overlays such as PPD and CCI for legibility and clarity. In the context of anonymised deliverables, artificial intelligence tools are increasingly employed by CROs to boost efficiency and meet tight deadlines, especially for critical tasks such as addressing EU-CTR requests for information. These tools enable MWs to produce high-quality clinical reports with reduced turnaround times. However, manual QC remains vital for logical consistency and accurate PPD and CCI identification and adding a human touch to anonymised clinical reports.

Documentation: Documentation of all these steps is an important aspect of medical writing. We need to document each step of the document cycle in a repository system for future reference

and audit readiness. These include approval emails, source documents, and other relevant conversations for future communication.

Conclusion

There needs to be a well-established collaboration between data controllers and data processors to succeed in delivering the strategic and time-sensitive tasks required for clinical report publication. The CRO MW upholds data protection regulations while striving for optimal data transparency and is pivotal in the implementation of robust anonymisation processes. They do this by leveraging artificial intelligence tools for efficiency and engaging cross-functional stakeholders to ensure a compliant and high-quality anonymisation package, as well as employing soft skills in stakeholder communication, such as ensuring leadership of the project, having the confidence to influence decision making, being well-organised and thinking ahead. Ultimately, this article emphasises the valuable role that MWs play in achieving transparency in clinical research and fostering a partnership with data controllers (clients or sponsors) to deliver high-quality anonymised documents.

Acknowledgements

The authors would like to express their sincere gratitude to James Wolfe for his critical review and valuable input on this article.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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